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PTO/SB/05 (4/98)
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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C.F.R. § 1.53(b))

Attorney Docket No.	PBLMD-51494
First Inventor or Application Identifier	G. Bourdon
Title	Pressure-Controlled Breathing Aid
Express Mail Label No.	EL372192158US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents.

ADDRESS TO: Assistant Commissioner for Patents
Box Patent Application
Washington, DC 20231

1. [X] * Fee Transmittal Form *(e.g., PTO/SB/17)*
(Submit an original and a duplicate for fee processing)
2. [X] Specification [Total Pages 14]
(preferred arrangement set forth below)
- Descriptive title of the Invention
- Cross References to Related Applications
- Statement Regarding Fed sponsored R & D
- Reference to Microfiche Appendix
- Background of the Invention
- Brief Summary of the Invention
- Brief Description of the Drawings *(if filed)*
- Detailed Description
- Claim(s)
- Abstract of the Disclosure

3. [X] Drawing(s) *(35 U.S.C. 113)* [Total Sheets 2]
4. Oath or Declaration [Total Pages 2]
a. [ ] Newly executed (original or copy)
b. [X] Copy from a prior application (37 C.F.R. § 1.63(d))
(for continuation/divisional with Box 16 completed)
i. [ ] DELETION OF INVENTOR(S)
Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).

** NOTE FOR ITEMS 1 & 13: IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28).*

5. [ ] Microfiche Computer Program *(Appendix)*
6. Nucleotide and/or Amino Acid Sequence Submission
(if applicable, all necessary)
a. [ ] Computer Readable Copy
b. [ ] Paper Copy (identical to computer copy)
c. [ ] Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

7. [ ] Assignment Papers (cover sheet & document(s))
8. [ ] 37 C.F.R.§3.73(b) Statement *(when there is an assignee)* [ ] Power of Attorney
9. [ ] English Translation Document *(if applicable)*
10. [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
11. [X] Preliminary Amendment
12. [X] Return Receipt Postcard (MPEP 503)
(Should be specifically itemized)
13. [ ] * Small Entity Statement(s) *(PTO/SB/09-12)* [ ] Statement filed in prior application, Status still proper and desired
14. [ ] Certified Copy of Priority Document(s)
(if foreign priority is claimed)
15. [X] Other: Copy of Assignment to Nellcor Puritan Bennett France Dev. (prior appln.)

16. If a CONTINUING APPLICATION, *check appropriate box, and supply the requisite information below and in a preliminary amendment:*

[X] Continuation [ ] Divisional [ ] Continuation-in-part (CIP) of prior application No: 08 / 793,956

Prior application information: Examiner V. Srivastava Group / Art Unit: 3735

For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

17. CORRESPONDENCE ADDRESS

[ ] *Customer Number or Bar Code Label* *(Insert Customer No. or Attach bar code label here)* or [XX] *Correspondence address below*

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Signature	Ronald E Perez	Date	May 7, 1999

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	Prior Examiner: V. Srivastava
Inventor: Guy Bourdon	Prior Art Unit: 3735
Serial No.:	Docket No. PBLMD-51494
Filed: Concurrently herewith	
For: PRESSURE-CONTROLLED BREATHING AID	**Express Mail No. EL372192158US**
Date: May 7, 1999	

PRELIMINARY AMENDMENT

BOX PATENT APPLICATION
Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

This Preliminary Amendment is being filed concurrently with a 1.53(b) Continuation Application, based upon Serial No. 08/793,956; filed March 12, 1997, which was filed from International Application No. PCT/FR95/01158; filed September 11, 1995.

Entry of the following amendments prior to examination of the application is respectfully requested.

IN THE SPECIFICATION:

At page 1, before the heading "DESCRIPTION", please insert:

--RELATED APPLICATIONS:

This is a continuation of Serial No. 08/793,956, filed March 12, 1997.--

IN THE CLAIMS:

Please cancel claims 2 to 15, without prejudice.

REMARKS

A subsequent preliminary amendment will be filed to add the claims for this continuation application.

Respectfully submitted,

FULWIDER PATTON LEE & UTECHT, LLP

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Pressure-controlled breathing aid

DESCRIPTION

The present invention relates to a pressure-controlled breathing aid.

Breathing aid devices - or ventilation devices - currently used in mechanical ventilation can be divided into two main groups, namely volumetric devices characterized by the supply of a specified volume in each respiratory cycle, and pressure-controlled devices characterized by the provision of a specified pressure in each respiratory cycle.

Volumetric devices have the advantage of guaranteeing a specified breathed volume, but they have major disadvantages. In particular, they expose the patient to risks of barotrauma as they tend to apply pressure which increases at the end of insufflation. Furthermore, the patient risks not being matched to the device in the sense that the respiratory reflexes of the patient can appear at different times from those at which the volumes imposed by the device finish being supplied.

On the contrary, pressure-controlled devices allow better synchronization of the patient with the device and avoid the risk of barotrauma since the maximum pressure supplied is known in advance. On the other hand, the volume supplied to the patient in each cycle and the breathed volume are not guaranteed.

The purpose of the present invention is to propose a breathing aid device which combines the advantages of both of the known ventilation modes discussed above.

According to the invention, the pressure mode breathing aid device, comprising means for supplying breathable gas to an inspiratory branch of a patient

circuit at an inspiratory pressure, is characterized by:

- means of measuring the breathed volume,
- means of comparing the breathed volume with a command, and
- regulation means to increase the inspiratory pressure in the case of a breathed volume lower than the command, and to reduce the inspiratory pressure in the case of a breathed volume higher than the command.

Thus, the pressure is adjusted in a direction tending to provide the predetermined volume applied as a command. In this way a volume is guaranteed without taking the risk of increasing the pressure in an uncontrolled manner, nor of creating the particular risk of mismatch between the breathing timing of the patient and that of the device. In particular, the invention is perfectly compatible with devices of the type described in FR-A-2 695 830 in which the device detects the respiratory reflexes of the patient in order to change from inspiratory phases to expiratory phases and vice-versa.

In order to prevent any risk of barotrauma, it is advantageous to provide means of setting a maximum predetermined pressure which the pressure applied to the patient will not be able to exceed even if the volume supplied is insufficient.

It is also advantageous to provide a signalling device or other alarm detecting the simultaneous occurrence of insufficient volume and the setting of the pressure at its maximum predetermined value, in order to signal this situation of the device's inability to provide the breathed volume set as a command.

In the framework of the present invention, the expression "breathed volume" is used to denote both the volume of the breathable gas inspired or expired per

unit time and the volume or quantity of gas inspired or expired per breathing cycle.

Preferably, the adjustment means apply to the inspiratory pressure a pressure variation which is equal in percentage to the difference between the inspiratory volume and the command.

However, in the case where an extreme value of pressure is predetermined and if the application of such a variation would result in exceeding the extreme value, the new inspiratory pressure is made equal to the extreme value of the pressure.

Other features and advantageous of the invention will furthermore emerge from the following description relating to non-limitative examples.

In the accompanying drawings:

- Figure 1 is a block diagram of a first embodiment of the device according to the invention;
- Figure 2 is an operational flowchart of the regulating means of the device of Figure 1; and
- Figures 3 and 4 are two block diagrams similar to Figure 1 but relating to two embodiments of the device according invention.

In the example shown in Figure 1, the breathing aid device comprises a patient circuit 1 which itself comprises a patient connection 2, namely a facial or nasal mask, or an intubation or tracheotomy tube, connected to an inspiratory branch 3 and to an expiratory branch 4 by the intermediary of a bidirectional branch 5. The expiratory branch 4 comprises an expiration device 6 which, in a way which is not shown, comprises an expiration valve and means of controlling this valve. The expiration valve is closed during the inspiratory phases of the patient's breathing. During the expiratory phases of the patient's breathing, the expiration valve can either be open so that the patient expires at atmospheric

pressure, or it can operate like a discharge valve to oblige the patient to expire at a certain predetermined excess pressure.

The inspiratory branch 3 is connected, at its end furthest from the mask 2, to a unit 8 for ventilation through inspiratory aid which comprises means, such as an adjustable speed motor-turbine set, for supplying breathable gas through the inspiratory branch 3 at an adjustable pressure, in the direction of the mask 2, means of detecting the patient's respiratory reflexes, for example from instantaneous flow rate variations, and means of controlling the expiration valve of the expiration means 6 and an inspiration valve placed in the inspiratory branch 3 in order to open the inspiration valve and to close the expiration valve during the inspiratory phase, and to close the inspiration valve and to release the expiration valve during the expiratory phases. Thus, in the inspiratory phase, the patient is connected in a gas-tight manner with the inspiratory branch 3, and the volume flowing in the inspiratory branch 3 corresponds to the volume of gas inspired. And during the expiratory phases, the patient is connected in a gas-tight manner with the expiratory branch 4 and the volume flowing in the expiratory branch 4 corresponds to the volume of gas expired.

Such inspiratory aid devices, or inspiratory aid devices of the same kind are described in the prior art, in particular in FR-A-2 695 830.

The ventilation unit 8 can comprise pressure control means by means of which the pressure P detected in the inspiratory branch 3 by a detector 10 is compared with a pressure command AI in order to adjust, for example, the speed of rotation of the motor-turbine set in the direction tending to make the pressure P equal to the command AI.

According to the invention, the breathing aid device comprises means 11 of regulating the patient's breathed volume. The regulating means 11 comprise a control unit 9 for controlling the pressure command AI which the ventilation unit 8 must apply to the inspiratory branch 3 during the inspiratory phases.

The regulating means 11 furthermore comprise a unit 12 for measuring the volume VTI inspired by the patient during each breathing cycle. The unit 12 provides the control unit 9 with a signal indicative of the volume VTI. The control unit 9 comprises an input 13 for receiving the signal VTI, and three inputs 14, 16, 17, allowing the user of the device to enter a minimum breathed volume command into the control unit, in the form of a minimum inspired volume per cycle VTImini, a minimum inspiratory pressure command AImini, and a maximum inspiratory pressure command AImaxi.

In general, the control unit 9 compares the measured volume VTI with the command VTImini and adjusts the pressure command AI in the direction tending to bring the measured volume VTI towards the command VTImini, without however causing the command AI to move outside of the range included between the two extreme values AImini and AImaxi. Within this range, the control unit 9 tends to increase the command AI when the measured volume VTI is lower than the command VTImini, and to reduce the pressure command AI in the opposite case.

When starting up the device, the commands VTImini and AImini are chosen such that the breathed volume VTI is established at a value higher than VTImini when the pressure command AI is equal to AImini. Thus, if the patient breathes as expected, the pressure command AI stabilises at AImini with a breathed volume above the minimum command VTImini. It is only in the event of a

breathing anomaly or incident, for example a partial obstruction of the breathing channels, that the measured breathed volume VTI is likely to become lower than VTImini, thus causing an increase in the command AI generated by the control unit 9. When the breathing becomes normal again, the breathed volume again becomes higher than the command VTImini, such that the control unit 9 returns the pressure command AI more or less rapidly to the value AImini.

The flowchart used by the control unit 9 will now be described in greater detail with reference to Figure 2. At the start, A1 is made to equal to AImini (step 18).

Then, at the end of each breathing cycle, or during each expiratory phase, the measurement VTI of the volume inspired during the preceding inspiratory phase is acquired (step 19) and is then compared with the command VTImini by the test 21. If the measured volume VTI is greater than or equal to VTImini, in other words if the volume inspired by the patient is satisfactory, a test 22 determines if the pressure command AI is or is not greater than the minimum AImini. If the pressure command is equal to the minimum, the conditions are therefore ideal (volume at least equal to the minimum, minimum pressure) and the sequence therefore returns directly to step 19 for acquiring the next inspired volume measurement. In the opposite case, advantage will be taken of the fact that the inspired volume is satisfactory in order to attempt to reduce the pressure command by a step 23 in which there is applied to the pressure command AI, expressed in relative value, a variation equal in percentage and opposite in sign to the difference between the measured inspired volume VTI and the command VTImini. The formula is such that, in the particular case in which the measured volume VTI is equal to VTImini, no modification is applied to the pressure command AI (0% variation).

Returning now to the test 21 on the measured volume VTI, if the latter is lower than the command VTImini, an attempt will be made to increase the pressure command AI in order to assist the patient more. But prior to this, by a test 24, it will be checked that the pressure command AI has not already reached the maximum AImaxi. If the answer is yes, an alarm is triggered (step 26) to indicate the necessity of an urgent intervention.

On the other hand, if the pressure command AI is not yet equal to AImaxi, the sequence returns as before to step 23 in which there will be applied to the command AI a variation equal in percentage and opposite in sign to the difference between the measured volume VTI and the command VTImini.

Before actually applying the command AI, reduced or increased such as it has been computed in step 23, to the input of the ventilation unit 8, it will firstly be checked, by a test 27, that the new computed AI value does not exceed the maximum AImaxi and, by a test 28, that it is not less than the minimum AImini.

If the new AI value has gone beyond one or other of these extreme values, the command AI which will be applied to the ventilation unit 8 will be equal to the extreme value in question (steps 29 and 31).

The example shown in Figure 3 will only be described where it differs with respect to the example shown in Figure 1.

In the example of Figure 3, the breathed volume is no longer measured by means of the volume inspired in each cycle but by means of the volume VTE expired in each cycle. For this purpose, the VTI measuring unit 12 in the inspiratory branch 3 has been eliminated and it has been replaced by a VTE measuring unit 32 in the expiratory branch 4.

The minimum breathed volume command applied to the control unit 9 is therefore the command VTEmini for the volume expired per cycle, in order to be able to be

compared directly with the measurement provided by the unit 32.

It can be advantageous to select, case by case, measurement of the inspired volume or measurement of the expired volume. This is the solution proposed by the embodiment shown in Figure 4, which will be described only where it differs with respect to the example shown in Figure 1.

The measuring unit 42 is this time installed in the bidirectional branch 5 of the patient circuit 1 and it comprises means 43 of selecting the direction of flow in which the volume is to be measured. In accordance with this selection, the unit 42 provides, by choice, a measurement of VTI or of VTE. In accordance with the operating mode of the measuring unit 42, the control unit 9 interprets the input applied at 14 as an inspired volume command or as an expired volume command. There is no longer any measuring unit in the inspiratory branch 3 nor in the expiratory branch 4.

In all of the described embodiments, the speed of execution of the flowchart in Figure 2 is sufficient for the measurement carried out in each breathing cycle to make it possible to correct the pressure applied during the following inspiratory phase. When the measurement is based on the expired volume, it is however possible that the pressure correction will occur only during, and not from the start, of the following inspiratory phase.

The invention is applicable to all ventilators capable of measuring the volumes delivered and of automatically controlling the value of the insufflation pressure.

The invention is applicable to all methods of ventilation using pressure control, and in particular to "inspiratory aid" and "controlled pressure" methods. Inspiratory aid is a method consisting in maintaining a substantially constant pressure in the patient circuit

during the insufflation, the patient initiating the start and end of the insufflation by his respiratory reflexes. The controlled pressure method is identical to the inspiratory aid method except that the patient does not initiate the end of the insufflation, the latter being determined by a fixed time.

It would also be conceivable for the control unit, instead of adjusting the pressure command AI applied to the ventilation unit, to adjust, for example, the speed of rotation of the motor turbine set, or the electrical power supplied to it. It would then be possible to avoid abnormal pressures in the inspiratory branch 3 by comparing the pressure in the inspiratory branch 3 with limits such as AImini and AImaxi, and by initiating a corrective modification of the speed or of the power of the motor turbine set in the case of exceeding, or of risk of exceeding such limits.

CLAIMS

1. Pressure mode breathing aid device, comprising means (8) for supplying breathable gas to an inspiratory branch (3) of a patient circuit (1) at an inspiratory pressure (AI), characterized by:

- means (12; 32; 42) of measuring the breathed volume (VTI, VTE),
- means of comparing the breathed volume (VTI; VTE) with a command (VTImini; VTEmini), and
- regulation means (11) to increase the inspiratory pressure (AI) in the case of a breathed volume lower than the command (VTImini; VTEmini), and to reduce the inspiratory pressure in the case of a breathed volume higher than the command (VTImini; VTEmini).

2. Device according to Claim 1, characterized in that in order to adjust the inspiratory pressure, the regulating means (11) adjust a pressure command applied to a regulated pressure ventilation unit (8).

3. Device according to Claim 1 or 2, characterized in that the means (12; 32; 42) for measuring the breathed volume measure the volume amount (VTI; VTE) which has been breathed by the patient during a breathing cycle, and the regulating means (11) are based on the result of the comparison (21) of this volume amount with the command in order to adjust the inspiratory pressure applied during a following cycle.

4. Device according to one of Claims 1 to 3, characterized in that the means (12; 42) of measuring the breathed volume measure the volume (VTI) inspired by the patient.

5. Device according to one of Claims 1 to 3, characterized in that the means (32; 42) of measuring

the breathed volume measure the volume (VTE) expired by the patient.

6. Device according to one of Claims 1 to 3, characterized in that the means (42) of measuring the breathed volume selectively measure the volume inspired (VTI) or the volume expired (VTE) by the patient.

7. Device according to Claim 4, characterized in that it comprises means (8) for connecting the inspiratory branch (3) in substantially gas-tight manner with the respiratory channels of the patient during inspiratory phases of the respiratory cycle and to interrupt the flow of breathable gas in the inspiratory branch (3) during expiratory phases of the respiratory cycle, and in that the means (12) of measuring the breathed volume are connected to the inspiratory branch (3).

8. Device according to Claim 5, characterized in that the patient circuit (1) comprises an expiratory branch (4) and in that the device comprises means (5) of connecting the expiratory branch (4) in a substantially gas-tight manner with the respiratory channels of the patient during expiratory phases of the respiratory cycle and to interrupt the flow of gas in the expiratory branch (4) during inspiratory phases of the respiratory cycle, and in that the means (32) of measuring the breathed volume are connected to expiratory branch (4).

9. Device according to Claim 6, characterized in that the patient circuit (1) comprises a bidirectional branch (5) to which are connected the inspiratory branch (3) and an expiration path (4), in that the means (42) of measuring the breathed volume are connected to the bidirectional branch and are capable of measuring the volume in both directions of flow, means (43) being provided to select the direction of the flow in which the breathed volume measuring means (42) measure the volume.

10. Device according to one of Claims 1 to 9, characterized in that the regulating means increase the inspiratory pressure (AI) in the cases of a breathed volume (VTI, VTE) less than the command where the inspiratory pressure (AI) is less than a predetermined maximum pressure (AImaxi).

11. Device according to one of Claims 1 to 10 characterized in that the regulating means reduce the inspiratory pressure (AI) in the cases of a breathed volume (VTI, VTE) higher than the command where the inspiratory pressure (AI) is greater than a predetermined minimum pressure (AImini).

12. Device according to one of Claims 1 to 11, characterized in that, in at least certain of the said breathed volume (VTI; VTE) cases below and above the command (VTImini; VTEmini), the regulating means apply to the inspiratory pressure a pressure variation which increases with the difference between the measured breathed volume (VTI, VTE) and the command (VTImini, VTEmini).

13. Device according to one of Claims 1 to 11, characterized in that, in at least certain of the said breathed volume cases (VTI; VTE) below and above the command (VTImini; VTEmini) the regulating means apply to the inspiratory pressure a pressure variation equal in percentage to the difference between the measured breathed volume (VTI; VTE) and the command (VTImini: VTEmini).

14. Device according to one of Claims 1 to 11, characterized in that, in at least certain of the said cases of breathed volume (VTI; VTE) below and above the command (VTImini; VTEmini), the regulating means compute a modified pressure and apply the modified pressure if the modified pressure does not go beyond a predetermined extreme value and make the inspiratory pressure equal to the predetermined extreme value if

the computed modified pressure goes beyond the predetermined extreme value.

15. Device according to Claim 10 or 14, characterized in that it comprises a means (26) of indicating the simultaneous occurrence of a breathed volume (VTI; VTE) below the command (VTImini) and an inspiratory pressure (AI) at least equal to a predetermined maximum pressure.

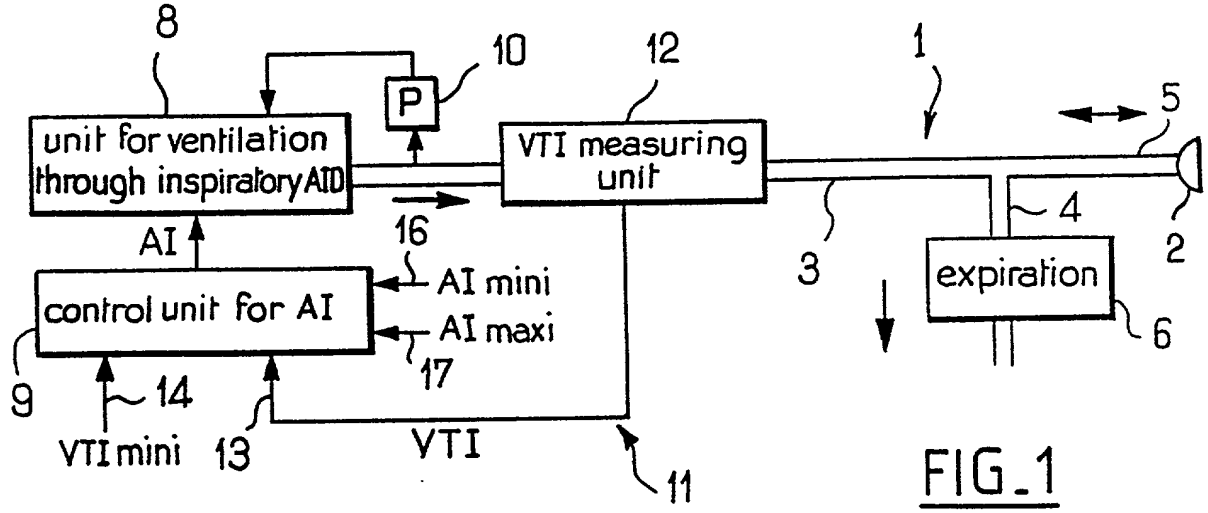

FIG_1

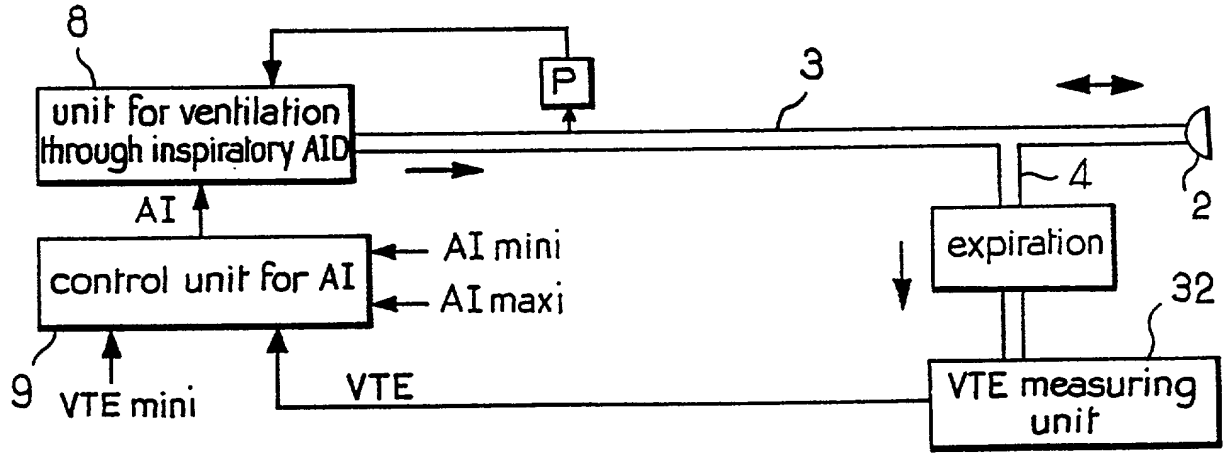

FIG_3

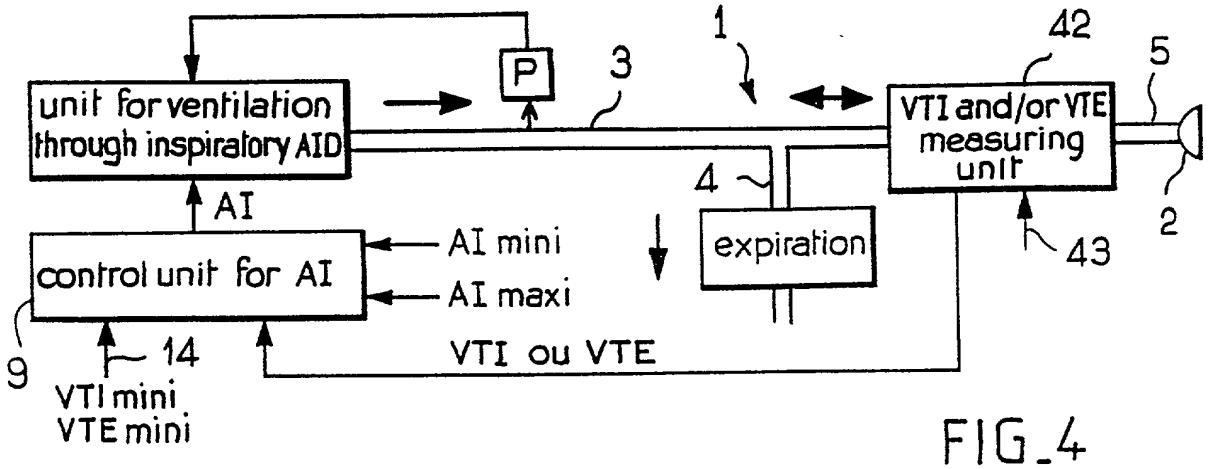

FIG_4

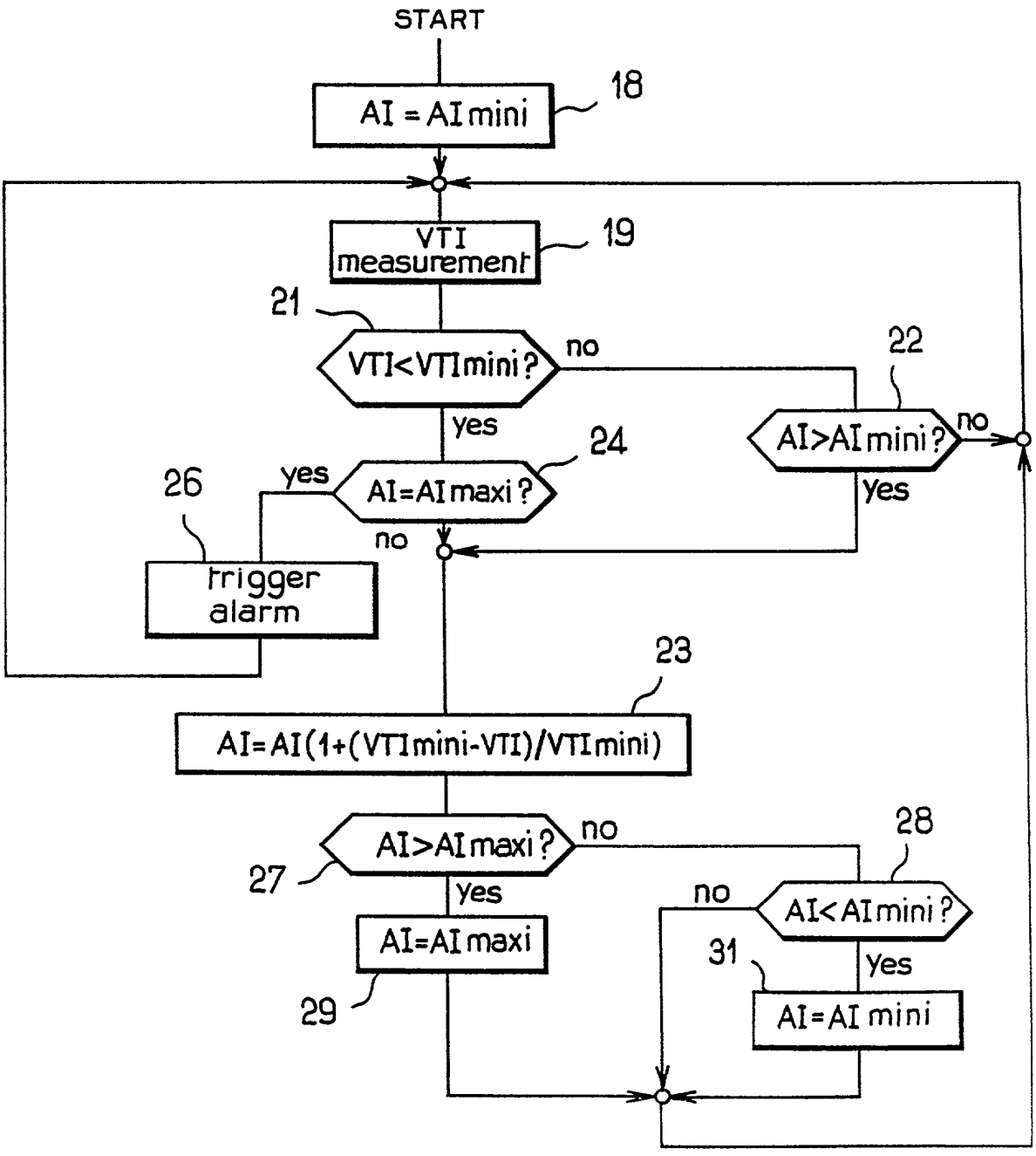

FIG_2

DECLARATION AND POWER OF ATTORNEY

As a below named inventor, I hereby declare:

That my residence, post office address and citizenship are as stated below next to my name:

That I verily believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a utility patent is sought on the invention entitled

PRESSURE-CONTROLLED BREATHING AID

the specification of which
(check one)

[ ] is attached hereto.

[X] was filed on 11th September 1995 as
Application Serial No. PCT/FR 95/01158
and was amended on 30th September 1996
(if applicable)

That I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

That I acknowledge the duty to disclose information which is material to the examination of this application in accordance with Title 37, Code of Federal Regulations, §1.56(a).

That I hereby claim foreign priority benefits under Title 35, United States Code, §119 and §172 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate on this invention having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s)			**Priority Claimed**
94 10839	FRANCE	12/09/1994	[X] [ ]
(Number)	(Country)	(Day/Month/Year)	Yes No
			[ ] [ ]
(Number)	(Country)	(Day/Month/Year)	Yes No
			[ ] [ ]
(Number)	(Country)	(Day/Month/Year)	Yes No

That I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application:

United States Application(s)

(Appl. Ser.No.)	(Filing Date)	(Status) (patented, pending, abandoned)
(Appl. Ser.No.)	(Filing Date)	(Status) (patented, pending, abandoned)

That all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful

false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

I hereby appoint the following attorneys, with full power of substitution and revocation, to prosecute this application and to transact all business in the United States Patent and Trademark Office connected therewith, and request that all correspondence and telephone calls in respect to this application be directed to GREER, BURNS & CRAIN, LTD., Suite 8660 - Sears Tower, 233 South Wacker Drive, Chicago, Illinois 60606, Telephone No. (312) 993-0080:

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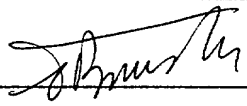
Lawrence J. Crain	31,497
Christopher J. Reckamp	34,414
Steven P. Fallon	35,132
James K. Folker (Agent)	37,538

Full name of sole or one joint inventor: Guy BOURDON

Inventor's signature: 

Date: 10th March 1997

Residence and Post Office Address: 6 route du Bua

F-91370 VERRIERES LE BUISSON, FRANCE

Citizenship: FRANCE

Full name of sole or one joint inventor: _____

Inventor's signature: _____

Date: _____

Residence and Post Office Address: _____

_____

Citizenship: _____